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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,881	01/09/2002	Peter Litschko	F-7212	5529

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EXAMINER
RAMANA, ANURADHA
ART UNIT
PAPER NUMBER

3732
DATE MAILED: 06/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/009,881	LITSCHKO ET AL.
	Examiner	Art Unit
	Anu Ramana	3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 November 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4 and 6 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Walker et al. (US 4,936,862).

Regarding claims 1 and 3-4, Walker et al. disclose a method of manufacturing individualized or “patient-specific” implants including the steps of: generating and storing an average joint bone or “virtual three-dimensional model” of the patient’s implant environment; comparing the virtual three-dimensional model to data collected from the patient or “real medical reference data” for an implant in a bone; generating a three-dimensional shape which represents the virtual three-dimensional model distorted or adjusted to conform to the contours and dimensions of the patient’s bone to create a surgically insertable prosthesis shape or “virtual implant model object”; and fabricating or manufacturing the prosthesis or implant by CNC (computer numeric control) techniques (col. 1, lines 13-20, col. 2, lines 40-68, col. 3, lines 1-11, col. 4, lines 11-68, col. 4, lines 1-68 and col. 6, lines 1-42).

Regarding claim 2, a database is an inherent data storage feature associated with computer-aided design software.

Regarding claim 6, Walker et al. disclose that the reference model object can be adjusted prior to fabrication based on the opinion of the attending surgeon or “medical expert” (col. 6, lines 54-64). Further, Walker et al. disclose that the dimensions of the patient’s bone can be radiographed on additional axes (“plurality of sets of reference data”) with adjustment of the “average bone” or virtual three-dimensional model(s) to generate a virtual implant model that is even closer to a patient’s bone (col. 6, lines 65-68 and col. 7, lines 1-5 and lines 31-56).

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Eufinger et al. (US 5,798,924).

Eufinger et al. disclose a process or "method" for producing an individually constructed endoprosthesis or implant including the steps of: generating a reference or "virtual three-dimensional" model; comparing the virtual three-dimensional model to an actual model or "real medical reference data"; performing interactive modeling and manipulating to generate a data block or "reference model object"; and manufacturing the implant from the reference model object utilizing a computer-controlled manufacturing unit (col. 1, lines 7-21, col. 4, lines 51-67, col. 5, lines 1-40).

Regarding claim 2, a database is an inherent data storage feature associated with computer-aided design software.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eufinger et al.

Regarding claim 6, although Eufinger et al. disclose manipulation of one reference model and one actual model to generate one reference model objects, it would have been obvious to one having ordinary skill in the art at the time the invention was made to generate a plurality of reference model objects based on a plurality of reference and actual models, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8. It is the Examiner's position that an expert in the related medical field can only perform the data manipulation taught by Eufinger et al.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicants' attention is specifically directed to Kennedy (SU 5,360,446): col. 1, lines 7-11, col. 2, lines 17-31, col. 3, lines 31-48, col. 7, lines 49-68 and col. 8, lines 1-44).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:30 am and 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AR *Anuradha Ramana*
June 10, 2003

Eduardo C. Robert
EDUARDO C. ROBERT
PRIMARY EXAMINER